

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MISSOURI  
SOUTHERN DIVISION**

**LESTER E. COX MEDICAL CENTERS  
d/b/a COX MEDICAL CENTERS, et al.,**

**Plaintiffs,**

**v.**

**AMNEAL PHARMACEUTICALS, LLC, et  
al.,**

**Defendants.**

**Case No. 6:22-cv-03192-MDH**

**PROTECTIVE ORDER**

Before the Court is the Joint Motion for Entry of Protective Order. (Doc. 164). The parties state they have met and conferred and jointly move the Court to enter the following Protective Order. The Court grants the motion and orders as follows:

**A. Scope of Protective Order**

1. This Protective Order applies to and governs the use, production, storage, handling, and disclosure of all products of discovery, including but not limited to, all hard copies and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, as captioned above (“the Litigation”). This includes: documents, information, things, electronically stored information, deposition testimony and exhibits, requests for production and responses to requests for production, interrogatories and responses to interrogatories, requests for admission and responses to requests for admission, expert reports and supporting data, and other information – including all copies, excerpts, and summaries thereof – produced, given, or supplied by any Party, nonparty, or any other individual or entity in connection with the Litigation (collectively, “Discovery Material”).

- a. This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.
- b. Third Parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.
- c. The entry of this Protective Order does not preclude any party from seeking a further order of this Court as appropriate.
- d. Nothing herein will be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.
- e. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential. The Court expects and will assume that the attorney submitting the designation has reviewed it and does so subject to all applicable rules of civil procedure and ethics.

**B. Use of Information**

Any Discovery Material produced by a Party or a non-party in this Litigation, including but not limited to any Discovery Material that is designated as “Confidential Health Information,” “Confidential,” “Highly Confidential” or “Highly Confidential—Attorneys’ Eyes Only,” as provided in Section C of this Protective Order, may be used only for purposes of this Litigation, including any appeals of this Litigation. Such Discovery

Material must not be used for any business, competitive, personal, private, or public purpose, or for any purpose other than this Litigation. Disclosure of Discovery Material is prohibited, except as expressly provided in this Protective Order.

### **C. Definitions**

**1. Discovery Material.** “Discovery Material” means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of “CONFIDENTIAL HEALTH INFORMATION,” “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL” or “HIGHLY CONFIDENTIAL—Attorneys’ Eyes Only” on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL HEALTH INFORMATION, CONFIDENTIAL, HIGHLY CONFIDENTIAL, or HIGHLY CONFIDENTIAL – Attorney’s Eyes Only is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding “CONFIDENTIAL HEALTH INFORMATION,” “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL,” or “HIGHLY CONFIDENTIAL – Attorney’s Eyes Only” designation.

**2. Designations – “Confidential Health Information,” “Confidential,” “Highly Confidential” and “Highly Confidential—Attorneys’ Eyes Only.”**

a. Any Party or non-party will have the right to identify and designate all or any part of a document, discovery response, deposition, or other Discovery Material which that party or person produces, serves, or provides in connection with the Litigation as

“Confidential Health Information” as defined in Section N below, “Confidential,” “Highly Confidential,” or “Highly Confidential—Attorneys’ Eyes Only” as described below.

i. “Confidential” means Discovery Material that any producing Party, including any third party, in good faith, believes falls within one or more of the following categories:

- (a) information prohibited from disclosure by any applicable federal or state laws, regulations, and statutes, including but not limited to the laws of the State of Missouri and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”);
- (b) information that reveals trade secrets;
- (c) proprietary non-public business information;
- (d) research, technical, commercial, or financial information that is not publicly available;
- (e) current and past (to the extent they reflect on current) methods, procedures, and processes related to the pricing of pharmaceuticals;
- (f) current and past (to the extent they reflect on current) business planning that is not publicly available;
- (g) medical information concerning any individual;
- (h) personal identity information (e.g., social security numbers);
- (i) income tax returns (including attached schedules and forms), W-2 forms, and 1099 forms;
- (j) personnel or employment records of a person who is not a party to the case;

- (k) protected law enforcement materials (including investigative files, overdose records, Narcan, coroner's records, court records, and prosecution files);
- (l) current and past research, development, production, and manufacturing information;
- (m) intellectual property; and
- (n) other information for which a good faith claim of need of protection can be made under the Missouri Rules of Civil Procedure and/or applicable law.

In addition, to the extent that a Designating Party produces Discovery Materials in this Litigation that were produced and designated as "Confidential" in *In re National Prescription Opioids Litigation*, Case No. 17-MDL-2804 (N.D. Ohio) (the "MDL proceedings") or related litigation, those Discovery Materials will be designated as "Confidential" under this Protective Order. In designating discovery materials as "Confidential," the Producing Party must do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein will be construed to allow for global designations of all documents or indiscriminate designation of documents as "Confidential."

ii. "Highly Confidential" is defined herein as information which, if disclosed, disseminated, or used by a Competitor of the Designating Party or any other person not enumerated in Section E and otherwise herein could reasonably result in possible antitrust violations or commercial, financial, or business harm, including non-public information consisting either of trade secrets or proprietary or

other highly confidential business, financial, regulatory or strategic information (including information regarding business plans, technical data and non-public designs) In addition, to the extent that a Producing Party produces Discovery Materials in this Litigation that were produced and designated as “Highly Confidential” in the MDL or factually related actions, these Discovery Materials will be deemed to be “Highly Confidential” under this Protective Order. In designating Discovery Materials as “Highly Confidential,” the Producing Party must do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein will be construed to allow for global designations of all documents or indiscriminate designation of documents as “Highly Confidential.”

iii. “Highly Confidential – Attorneys’ Eyes Only Information” is defined herein as information properly designated as “Highly Confidential” that the Designating Party reasonably and in good faith believes is so highly sensitive and is of such a nature that disclosure to persons other than those listed in Section E(4) would create substantial risk of economic injury. In addition, to the extent that a Producing Party produces Discovery Materials in this Litigation that were produced and designated as “Highly Confidential – Attorneys’ Eyes Only Information” in the MDL proceedings or factually related actions, those Discovery Materials will be deemed to be “Highly Confidential Information – Attorneys’ Eyes Only” Information under this Protective Order. In designating Discovery Materials as “Highly Confidential – Attorneys’ Eyes Only” Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and

rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents or indiscriminate designation of documents as “Highly Confidential – Attorneys’ Eyes Only” Information. To the extent documents in this Litigation have already been produced and designated “Highly Confidential – Attorneys’ Eyes Only,” those documents will be entitled to the protections of this Order.

- b. The fact that Discovery Materials were produced and designated as “Confidential,” “Highly Confidential,” or “Highly Confidential—Attorneys’ Eyes Only” in the MDL proceedings does not preclude a good faith challenge to the propriety of such designation in this Litigation.
- c. A Party may designate Discovery Material as “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential—Attorneys’ Eyes Only” notwithstanding the fact that the designated materials may be in the possession of a different Party or a third party. In this Protective Order, “Confidential Health Information,” “Confidential,” “Highly Confidential,” and/or “Highly Confidential – Attorneys’ Eyes Only Information,” Discovery Materials are referred to collectively as “Protected Material.”
- d. A Party (or, if applicable, non-party), including but not limited to a Producing Party, that designates Discovery Material as “Confidential Health Information,” “Confidential,” “Highly

Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” will be referred to as the “Designating Party.” Any Party (or, if applicable, non-party), and all employees, agents, and directors (other than Counsel) of the Party receiving Discovery Material covered by this Order will be referred to as the “Receiving Party.” If additional parties are added other than parents, subsidiaries or affiliates of current parties to, then their ability to receive Discovery Material designated Confidential Health Information, Confidential, Highly Confidential, or Highly Confidential – Attorneys’ Eyes Only as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

**3. Definitions:**

- a. **Designating Party.** A Party (or, if applicable, non-party) producing information covered by this Order shall be referred to as the “Designating Party.”
- b. **Receiving Party.** Any Party (or, if applicable, non-party) receiving Discovery Material covered by this Order shall be referred to as the “Receiving Party.”
- c. **Competitor.** Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving



opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Section H and otherwise herein is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant, except as provided herein.

- d. **In-House Counsel.** “In-House Counsel” means attorney employees of any Party.
- e. **Counsel.** “Counsel,” without another qualifier, means Outside Counsel and In- House Counsel.
- f. **Outside Counsel.** “Outside Counsel” means any law firm or attorney who represents any Party for purposes of this Litigation.
- g. **Party.** “Party” means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added to this Litigation other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Protected Material as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.
- h. **Producing Party.** “Producing Party” means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party, or

any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to Section A and otherwise herein.

- i. **Retained Consultant:** Retained Consultant means a subject-matter expert and/or independent consultant formally retained and/or employed to advise or assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Protected Material for the purpose of this Litigation.
- j. **Protected Material.** “Protected Material” means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that are designated as “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” in accordance with this Protective Order.

**D. Designation and Redaction of Confidential Discovery Material**

- 1. For each document produced by the Producing Party in hard copy that contains or constitutes “Confidential Health Information,” “Confidential,” “Highly Confidential” or “Highly Confidential – Attorneys’ Eyes Only” Information pursuant to this Protective Order, each page must be marked “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or with comparable notices. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or

tapes) (“Computerized Material”) is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of “CONFIDENTIAL HEALTH INFORMATION—SUBJECT TO PROTECTIVE ORDER,” “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” on the media. To the extent that a Producing Party produces Discovery Materials in this Litigation that were produced in the MDL proceedings or other factually related proceedings, those Discovery Materials shall be produced in the same manner and format previously produced in the MDL or other proceedings and bearing the same confidentiality designations.

2. Specific discovery responses produced by the Producing Party may, if appropriate, be designated as Confidential Health Information, Confidential Information, Highly Confidential Information, or Highly Confidential – Attorneys’ Eyes Only Information by marking the pages of the document that contain such information with the notation “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—ATTORNEYS’ EYES ONLY INFORMATION” or with comparable notices

3. For each document produced by the Producing Party that contains or constitutes “Confidential Health Information,” “Confidential,” “Highly Confidential” or “Highly Confidential – Attorneys’ Eyes Only” Information pursuant to this Protective Order, each page shall be marked “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,”

“HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or with comparable notices.

4. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation “CONFIDENTIAL HEALTH INFORMATION,” “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or with comparable notices.

5. Discovery Material disclosed through testimony at a deposition taken in connection with this Litigation may be designated as “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only”, by designating the portions of the transcript in a letter to be served on the court reporter and opposing Counsel within thirty (30) calendar days of the Producing Party’s receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as “Confidential Health Information,” “Confidential,” “Highly Confidential,” “Highly Confidential – Attorneys’ Eyes Only” Protected Material and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter must clearly mark any transcript released prior to the expiration of the 30 -day period as “HIGHLY CONFIDENTIAL—ATTORNEYS’ EYES ONLY INFORMATION—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW.” Such transcripts will be treated as “Highly Confidential – Attorneys’ Eyes Only” Protected Material until the expiration of the 30-day period. If the Producing Party does not serve a

designation letter within the 30-day period, then the entire transcript will be deemed not to contain Protected Material and the “HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW” legend must be removed.

6. In accordance with this Protective Order, only the persons identified under Section E and otherwise herein, along with the witness and the witness’s Counsel may be present if any questions regarding Protected Material are asked. This paragraph will not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

7. A Party in this Litigation may designate as “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” Protected Material any document, material, or other information produced by, or testimony given by, any other person or entity that the Party reasonably believes qualifies as the Party’s Protected Material pursuant to this Protective Order. The Party claiming confidentiality must designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party must treat such information as Highly Confidential – Attorneys’ Eyes Only Protected Material during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as Protected Material. Any Party designating third party information as Protected Material will have the same rights as a Producing Party under this Protective Order with respect to such information.

8. This Protective Order will not be construed to protect from production or to permit the “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” Protected Material designation of any

document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

9 A Producing Party may redact or de-identify certain Protected Material from produced documents, materials, or other things. The basis for any such redaction or de-identification must be stated in the Redaction field of document pursuant to the ESI Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact or de-identify:

- a. **Personal Identifying Information.** The names, home addresses with the exception of zip code designations, personal email addresses, home telephone numbers, cellular telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (1) current and former employees (other than employees' names and business contact information) (2) individuals in clinical studies or adverse event reports whose identity is protected by law, (3) undercover law enforcement personnel and confidential informants.<sup>1</sup>
- b. **Privileged Information.** Information protected from disclosure by the attorney-client privilege, work -product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The

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<sup>1</sup> Patient identifying information is addressed in Section N, *infra*.

obligation to provide and the form of privilege logs will be addressed by separate Order.

- c. **Third Party Confidential Information.** If agreed to by the Parties or ordered by the Court, information that is protected pursuant to confidentiality agreements between Producing Parties and third parties, as long as the agreements require Producing Parties to redact such information to produce such documents in litigation.
- d. The fact of redacting or withholding does not create a presumption that the redaction or withholding is valid and Receiving Parties can challenge redactions freely after providing appropriate notice to the Designating Party and (if applicable) the agency asserting the privilege or confidentiality redaction.

10. To the extent any document, materials, or other things produced contain segregated, non-responsive Protected Material concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this Litigation), the Producing Party may redact that segregated, non-responsive Protected Material except (a) if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product would render the information pertaining to the Producing Party's opioid product meaningless or would remove the context of the information about Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph will restrict Plaintiffs' right

and ability to request information about such other products nor does it restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

11. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted must be treated as Confidential, regardless of whether the document containing such names is designated as Protected Materials. No such person may be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

**E. Access to Protected Material**

1. General. The Receiving Party and Counsel for the Receiving Party must not disclose or permit the disclosure of any Protected Material to any third person or entity except as set forth herein.

2. In the absence of written permission from the Designating Party or an order of the Court, any Confidential information produced in accordance with the provisions of this Protective Order must be used solely for purposes of this Litigation as provided herein and its contents must not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such Counsel;
- b. Vendor agents retained by the Parties or Counsel for the Parties, provided that the vendor agrees to be bound by this Protective Order and completes



the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown Confidential information prepared after the date of their departure only to the extent Counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph will be deemed to permit the showing of one Defendant's Confidential information to an officer, director, or employee of another Defendant, except to the extent otherwise authorized by this Order;
- e. Videographers, stenographic employees, and court reporters recording or transcribing testimony in this Litigation;
- f. The Court any Special Master if one is appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Retained Consultants, and their staff, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

- i. Those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
  - j. Witnesses during deposition, who may be shown, but must not be permitted to retain, Confidential information; provided, however, that unless otherwise agreed by the relevant Parties or ordered by the Court or Special Master if one is appointed, no Confidential information of one Defendant may be shown to any witness who is a current employee of another Defendant who is not otherwise authorized to receive the information under this Order.
3. In the absence of written permission from the Designating Party or an order of the Court, any “Highly Confidential” Information produced in accordance with the provisions of this Protective Order must be used solely for purposes of this Litigation and its contents must not be disclosed to any person unless that person falls within at least one of the following categories:
- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such Counsel. Information designated as Highly Confidential by any Party may be disclosed to In-House Counsel of another Party, provided that the In-House Counsel:
    - i) has regular involvement in the Litigation,

- ii) disclosure to the individual is reasonably necessary to this Litigation, and
  - iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound.
- Except as otherwise provided in this Order or any other Order in this Litigation, no other employees of a Defendant may receive the Highly Confidential Information of another;
- b. Vendor agents retained by the Parties or Counsel for the Parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties that have produced the Highly Confidential Information;
- d. Videographers, stenographic employees, and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master if one is appointed by the Court and any members of their staffs to whom it is necessary to disclose the information;
- f. Retained Consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgement and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared or previously reviewed or received the Highly Confidential Information; and,

- h. Witnesses during deposition, who may be shown, but must not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Protective Order.

4. In the absence of written permission from the Designating Party or an order of the Court, any “Highly Confidential – Attorneys’ Eyes Only” Information produced in accordance with the provisions of this Protective Order must be used solely for purposes of this Litigation and its contents must not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel for the Parties and the attorneys, paralegals, stenographic, and clerical staff employed by such Counsel;
- b. Vendor agents retained by the Parties or Counsel for the Parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Videographers, stenographic employees, and court reporters recording or transcribing testimony in this Litigation;
- d. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

- e. Retained Consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound; and
- f. Any individual(s) who authored, prepared or previously reviewed or received the information.

5. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential or Highly Confidential – Attorneys’ Eyes Only Information being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party must excuse himself or herself from the deposition room without delaying or disrupting the deposition. In the event that In-House Counsel intends to attend any deposition at which there is reason to believe that Competitor’s Highly Confidential or Highly Confidential – Attorneys’ Eyes Only Information may be used, counsel shall advise In-House Counsel of this requirement prior to the Deposition.

**F. Confidentiality Acknowledgment**

Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, must be provided with a copy of this Protective Order, which he or she must read, and, upon reading this Protective Order, must sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party must maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is

hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Protected Material for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

**G.     Litigation Experts and Consultants.**

1.     Retained Consultants. Subject to the provisions of this Protective Order, all Protected Material may be disclosed to any formally retained consultant who has agreed in writing as provided herein or on the record of a deposition to be bound by this Protective Order. The party retaining a consultant must use diligent efforts to determine if the retained consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any Protected Material to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") must provide to Counsel for the Producing Party in writing, which may include by email, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure. The specific name of the retained consultant need not be provided. The Producing Party will have seven (7)

days from its receipt of the notice to deliver, including by e-mail, to the Notifying Party its good faith written objections (if any) to such disclosure to the expert or consultant.

2. Absent timely objection, the retained consultant may be allowed to receive Protected Material pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or consultant must not be made. If the Notifying Party desires to challenge the Producing Party's written objection to disclosure to the retained consultant, the Notifying Party must so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The retained consultant will then be allowed to receive Protected Material pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven (7) day period, the Producing Party seeks relief from the Court or Special Master if one is appointed, or the Parties stipulate to an agreement. Once a motion is filed, disclosure may not occur until the issue is decided by the Court and, if the motion is denied, the applicable appeal period from the Court order denying the motion has expired. In making such motion, it will be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

#### **H. Protection and Use of Confidential Discovery Material**

1. Persons receiving or having knowledge of Protected Material by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Protected Material only as permitted by this Protective Order. Counsel shall take

reasonable steps to assure the security of any Protected Material and will limit access to such material to those authorized by this Protective Order.

2. All persons qualified to receive Protected Material pursuant to this Protective Order must at all times keep all notes, abstractions, or other work product derived from or containing Protected Material in a manner to protect it from disclosure in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned or destroyed in accordance with this Protective Order. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

3. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Protected Material and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel shall not disclose any other Party's Protected Material other than in a manner provided for in this Protective Order.

4. Nothing contained in this Protective Order prejudices in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, or admissible into evidence at any deposition, at trial, or in a hearing.



5. Nothing herein shall restrict a person qualified to receive Protected Material pursuant to this Protective Order from making working copies, abstracts, digests, and analyses of such information, each of which shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

6. Nothing contained in this Protective Order precludes any Party from using its own Protected Material in any manner it sees fit, without prior consent of any Party or the Court.

7. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

8. If a Receiving Party learns of any unauthorized disclosure of Protected Material, it must immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Protected Material; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

9. Within One Hundred Twenty (120) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party must return all Protected Material under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;<sup>2</sup> or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Receiving Party elects to destroy the documents and certifies to the Producing Party that it has done so by providing a certificate of destruction in the form of Exhibit B attached hereto.

10. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' Outside Counsel and Defendants' Outside Counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Protected Material will continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose Protected Material.

#### **J. Changes in Designation of Information**

1. If a Party through inadvertence produces any Protected Material without labeling or marking or otherwise designating it as such in accordance with the provisions

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<sup>2</sup> With the exception of Confidential Health Information, which is further addressed in Section N, the Parties may choose to agree that the Receiving Party must destroy documents containing Protected Material and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Protected Material contained in deposition transcripts or drafts or final expert reports.

of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” Information, and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information will not be deemed a violation of this Protective Order. Any Producing Party may designate as “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” Information” or withdraw such designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation is effective only as of the date of such redesignation. Such redesignation is accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as “Confidential Health Information,” “Confidential,” “Highly Confidential,” or “Highly Confidential – Attorneys’ Eyes Only” Information the Receiving Party must (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this Protective Order; and (iii) promptly

endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

2. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Protected Material, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must (a) give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain in writing within seven (7) days the basis of the chosen designation, and (b) offer to provide the Producing Party with multiple alternatives (dates and times) to meet and confer during the seven (7) day period following the date of the Receiving Party's written challenge notification. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it must notify the Producing Party and the Receiving Party will have ten (10) days from such notification to challenge the designation by commencing a discovery dispute under appropriate procedures. These time periods may be modified in emergent circumstances, as agreed to by the Producing and Receiving Parties, or as ordered by the Court. The ultimate burden of persuasion in any such challenge proceeding will be on the Producing Party as if the Producing Party were seeking a Protective Order in the first instance. Until the Court rules

on the challenge, all Parties must continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the event that a designation is changed by the Producing Party or by Court Order, the Producing Party must provide replacement media, images, and associated production information as provided above.

**K. Inadvertent Production of Documents**

1. Non-Waiver of Privilege. The Parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) will be deemed inadvertent without need of further showing and will not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party").

2. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it will promptly notify the Receiving Party of the production in writing, identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Disclosing Party, the Receiving Party must immediately refrain from examining the information and must promptly notify the Disclosing Party in writing that the Receiving Party possesses potentially Privileged Information. The Disclosing Party will have seven (7) days to assert privilege over the

identified information. If the Disclosing Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

3. Recall of Privileged Information. If the Disclosing Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party is Privileged Information, the Receiving Party must within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Disclosing Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party.

4. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party must not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue. The Disclosing Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

5. Within fourteen (14) days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted (“Clawed-Back Information”), the Disclosing Party must produce a privilege log with respect to the Clawed-Back Information. Within fourteen (14) days after receiving the Disclosing Party’s privilege log with respect to such Clawed-Back Information, a receiving party may notify

the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within fourteen (14) days of the receipt of such notification, the Disclosing Party and the objecting party must meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The Parties may stipulate to extend the time periods set forth in this paragraph.

6. If, for any reason, the Disclosing Party and Receiving Party do not resolve their disagreement after conducting the required meet and confer, the Receiving Party may initiate an appropriate motion or procedure to challenge the privilege or protection claim with the Court. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

7. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

8. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Order shall control

9. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably

should know to be privileged and to inform the Disclosing Party that such materials have been produced.

**L. Filing and Use at Trial of Protected Material**

1. A party must seek, and be granted, leave of Court prior to filing a document under seal. If granted leave by the Court, a party may file a document under seal in accordance with the procedures outlined in the CM/ECF Civil and Criminal Administrative Procedures Manual and Users Guide for the Western District of Missouri (Revised January 2018) with access restricted to the Judge and authorized staff by filing the document using the corresponding sealed document event, i.e. (Motion for Order (Sealed); Suggestions in Support (Sealed), etc.) and emailing a copy of the document to opposing counsel (because the document cannot be accessed by counsel through the ECF system). Notification of the filing of the sealed document along with the docket entry for the filing is publicly displayed.

2. A Party that intends to present Protected Material at a hearing must bring that issue to the Court's and Parties' attention without publicly disclosing the Protected Material. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Protected Material at the hearing.

**M. Confidential Discovery Material Requested by Third Party; Procedure Following Request.**

1. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Protected Material that was produced by a person or entity other than the Receiver ("Request"), the Receiver must so notify the Designating Party immediately in writing and in no event more than five (5)



business days after receiving the Request. Such notification must include a copy of the Request.

2. The Receiver also must immediately inform the party who made the Request (“Requesting Party”) in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Designating Party.

3. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Protected Material. The Designating Party will bear the burden and the expense of seeking protection of its Protected Material, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Protected Material by the other Parties in this Litigation.

4. Protected Material must not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the “Public Disclosure Laws”), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks

a protective order, the Receiving Party must not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph do not apply to materials that (i) the Designating Party expressly consents in writing to disclosure, or (ii) this Court has determined by court order to have been improperly designated as Protected Material. The provisions of this section apply to any entity in receipt of Protected Material governed by this Protective Order. Nothing in this Protective Order will be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

**N. HIPAA-Protected Information**

1. General. This Protective Order authorizes the disclosure of information protected by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), including all applicable regulations and guidance issued by the Secretary of the United States Department of Health and Human Services (collectively “HIPAA Rules”), including, specifically, 42 C.F.R. Part 2 and 45 C.F.R. §§ 164.512(e)(1)(ii)(B), 164.512(e)(1)(v), as well as all state laws and regulations regarding the privacy and security of personal information (collectively with the HIPAA Rules, “Privacy and Security Rules”). This Protective Order constitutes a Qualified Protective Order, as that term is defined in the Privacy and Security Rules.

2. “Confidential Health Information” means information that is of the type protected under state or federal law, or where such protection is necessary to protect the privacy of the patient/insured/member, including, but not limited to, patient/insured/member medical records, patient/insured/member claims information, and other information that the Parties have determined might contain sensitive personal health information. Confidential Health Information encompasses any patient health information protected by state or federal law, including, but not limited to, “Protected Health Information,” as defined below.

(a) “Protected Health Information,” as used here, has the same scope and definition as set forth in 45 C.F.R. Parts 160 and 164. Without limiting the generality of this Section, Protected Health Information includes, but is not limited to, health information, including demographic information, relating to: the past,

present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, which identifies or reasonably could be expected to identify the individual. It also includes, but is not limited to, medical bills, claims forms, charges sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanation of benefits, checks, notices, and requests, and includes all notes, summaries, compilations, extracts, abstracts, or oral communications that are based on or derived from Protected Health Information, regardless of form or format. Protected Health Information also includes information that contains the following identifiers of a patient/insured/member or of a relative, employer, or household member of a patient/insured/member, to the extent it is linked to Protected Health Information as defined in 45 C.F.R. § 160.103:

- i). Names;
- ii). All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code;
- iii). All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, age, and date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- iv). Telephone numbers;

- v.) Fax numbers;
- vi). Electronic mail addresses;
- vii). Social security numbers;
- viii). Medical record numbers;
- ix). Health plan beneficiary numbers;
- x). Account numbers;
- xi). Certificate/license numbers;
- xii.) Vehicle identifiers and serial numbers, including license plate numbers;
- xiii). Device identifiers and serial numbers;
- xiv). Web universal resource locators (“URLs”);
- xv). Internet protocol (“IP”) address numbers;
- xvi). Biometric identifiers, including finger and voice prints;
- xvii). Full face photographic images and any comparable images;
- xviii). Any other unique identifying number, characteristic, or code; and
- xix). Any other identification that the Producing Party knows could be used alone or in combination with other information to identify an individual who is the subject of the information.

(b) Confidential Health Information does not include any document or information in which the Producing Party has redacted the identifiers listed above and does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.

(c) The Parties also seek to ensure that any person who receives and stores Confidential Health Information in connection with this Litigation will develop, implement, maintain, and use appropriate administrative, technical, and physical safeguards to preserve the privacy, integrity, and confidentiality of any Confidential Health Information, and to prevent unpermitted use or disclosure of any Confidential Health Information they may receive from any person in connection with this Litigation. At a minimum, all Parties and persons or entities who might receive Confidential Health Information agree that they will (1) comply with the Privacy and Security Rules, as defined in Section N and otherwise herein; (2) establish contractual controls that require any vendors, experts, or third parties that might receive Confidential Health Information to comply with the Privacy and Security Rules; and (3) undertake due diligence to verify that the privacy and security protections of any such vendors, experts, or third parties comply with the Privacy and Security Rules. Confidential Health Information will be securely returned or destroyed under the provisions of Section I and otherwise herein.

3. The Parties agree to make reasonable efforts to limit their requests for or use or disclosure of Protected Health Information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request consistent with 45 C.F.R. § 164.502(b). The Parties acknowledge the standards articulated at 45 C.F.R. § 164.514(a), (b), and (d).

4. Any Party who produces Protected Health Information in this Litigation must designate such Discovery Material “Confidential Health Information” in accordance with the provisions of this Protective Order.

5. Patient identifying information defined by 42 CFR § 2.11 shall be de-identified by producing patient data in a consistent encrypted form with newly-assigned random numbers given to each unique individual patient such that the newly assigned anonymized numbers can be tracked and function as a substitute for the patient medical record number. For each unique individual patient (as identified by underlying medical record number), the Disclosing Party shall use the same anonymized number in all of the Disclosing Party's productions.

6. Unless otherwise agreed between Counsel for the Parties, the designation of Discovery Material as "Confidential Health Information" must be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as "Confidential Health Information" made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of Discovery Material as "Confidential Health Information" must be made in the following manner: (a) on documents, by placing the notation "Confidential Health Information" or similar legend on each page of such document; (b) for tangible things, by placing the notation "Confidential Health Information" on the object or container thereof or if impracticable, as otherwise agreed by the Parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation "Confidential Health Information" both on the face of such document and on any particular designated

pages of such document; and (d) for testimony, by orally designating such testimony as being “Confidential Health Information” at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing Counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Litigation to those persons and for such purposes as designated herein. Further, all Parties that are entities subject to state privacy law requirements<sup>3</sup>, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Litigation to those persons and for such purposes as designated herein, or by further Order of the Court. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more Parties to the proceedings.

7. The Parties must not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may disclose Protected Health Information to: (a) Outside Counsel for the Parties in this action, (b) In-House Counsel for defendants in this action with responsibility for overseeing this Litigation, (c) the Court and its personnel, (d) Court reporters, and (e) consulting and testifying experts retained specifically to provide services in this action. No other

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<sup>3</sup> Mo. Rev. Stats 192.067; 191.317; 208.120; 208.155; 630.140; 198.032; 354.515; 537.035; 375.1309; 191.928; 188.055; 191.656; 192.739; 192.655; 199.033; and 13 CSR 70-1.020.



individuals are permitted to access protected health information, and all parties must institute reasonable and appropriate steps to prevent against unauthorized disclosure.

8. In the event that any Party learns of the unauthorized disclosure of Protected Health Information subject to this order, such Party must provide prompt notification of the breach to all Parties' Counsel, with such notice to include (1) the date of the breach, (2) the circumstances of the breach, (3) the identity or identities of the unauthorized recipients, (4) all steps taken or planned to remedy the breach, and whatever other notice requirements are necessary pursuant to federal or Missouri statutes or law.

9. Within sixty (60) days after dismissal or entry of final judgment not subject to further appeal, the Parties, their Counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order must destroy or return to the Covered Entity or Business Associate such Protected Health Information.

10. Nothing in this Order authorizes the Parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

11. This Order does not limit the rights of any Party to oppose any redactions or to seek appropriate discovery of Confidential Health Information or Protected Health Information, including in an unredacted and non-de-identified form, or to seek relief from the Court ordering such discovery. This provision should not be construed as a waiver of any Party's objections.

**O. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.**

In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party,

the Party must, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party must refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party must promptly produce the information in question subject to the protections of this Protective Order, or alternatively, must promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

**P. Miscellaneous Provisions**

1. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

2. Any deadline or time in which a particular action must be taken as set forth in this Protective Order may be extended upon agreement of the Parties and without intervention by or further Order of the Court.

3. Nothing in this Protective Order abridges the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

4. In the event anyone violates or threatens to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party applies for injunctive relief, the respondent person, subject to the provisions of this Protective Order, must not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

5. This Protective Order must not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery Material.

6. This Protective Order may be amended in the form of a written stipulation filed with the Court. The Protective Order will continue in force until amended or superseded by express order of the Court and will survive and remain in effect after the termination of this Litigation.

**IT IS SO ORDERED.**

DATED: March 23, 2023

/s/ Douglas Harpool  
DOUGLAS HARPOOL  
UNITED STATES DISTRICT JUDGE